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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,079	YAMAMOTO, JANET K.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed November 10, 2003 is acknowledged and entered. Claims 18-107 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 18-63, drawn to a cell line, classified in class 435, subclass 325.

II. Claims 64-97, drawn to a method of inducing an immune response, classified in class 935, subclass 65.

III. Claims 98-99, drawn to a method for detecting or determining the quantity of FIV viral neutralization antibodies in a sample, classified in class 435, subclass 7.9.

IV. Claim 100, drawn to an antibody, classified in class 424, subclass 130.1.

V. Claims 101-104, drawn to a method for identifying a target FIV strain, classified in class 435, subclass 7.1.

- Further restriction is required if Group V is elected. Applicant must choose one oligonucleotide primer set from claim 103.

VI. Claim 105, drawn to an oligonucleotide, classified in class 536, subclass 23.1.

- Further restriction is required if Group VI is elected. Applicant must choose one oligonucleotide sequence from claim 105.

VII. Claim 106, drawn to an FIV peptide, classified in class 424, subclass 207.1.

- Further restriction is required if Group VII is elected. Applicant must choose one amino acid sequence from claim 106.

VIII. Claim 107, drawn to an antibody that binds an FIV peptide, classified in class 424, subclass 148.1.

- Further restriction is required if Group VIII is elected. Claim 107 is drawn to an antibody that binds the peptide claimed in 106. Applicant must choose one peptide sequence from claim 106.

3. The inventions are distinct, each from the other because of the following reasons:

a) Restriction between amino acid sequences and nucleotide sequences is required because the sequences are comprised of different amino acids and nucleotides. Each sequence requires a separate search, which is burdensome.

b) Inventions I, IV, VI, VII and VIII are all unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a cell line, an antibody that binds to a cell line, an oligonucleotide, an FIV peptide and an antibody that binds an FIV peptide. Cells, antibodies, oligonucleotides and peptides are structurally and chemically distinct. The antibodies are distinct because one of them binds to a cell line and the other antibody binds to an FIV peptide. These products are not disclosed as capable of use together, nor do they share modes of operation, function and effect.

c) Inventions II, III and V are all unrelated to each other. The inventions are drawn to a method of inducing an immune response, a method for detecting or determining the quantity of FIV neutralization antibodies and a method for identifying a target FIV strain. These methods

have different modes of operation, function and effect. They are not disclosed as capable of use together.

d) Inventions I and (II and III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in two materially different processes such as inducing an immune response and detecting antibodies.

e) Inventions I and V are unrelated. The inventions are drawn to a cell line and a method for identifying a target FIV strain. The method does not require the use of the cell line and is not disclosed as capable of use with the cell line.

f) Inventions (IV, VII and VIII) and (II, III and V) are unrelated. Inventions IV, VII and VIII are drawn to an antibody that binds a cell line, an FIV peptide and antibody that binds an FIV peptide. Inventions II, III and V are methods of inducing an immune response, detecting antibodies and identifying an FIV strain. The methods do not require the use of the products and they are not disclosed as capable of use together.

g) Inventions VI and (II and III) are unrelated. Invention VI is drawn to an oligonucleotide. Inventions II and III are drawn to methods of inducing an immune response and detecting FIV antibodies. These methods do not require the use of the oligonucleotide, nor are they disclosed as capable of use together.

h) Inventions V and VI are related as product and process of use. The product, an oligonucleotide, can be used in a materially different process of using, such as inducing an immune response.

Because these inventions are distinct for the reasons given above and the literature and sequence search required for one group is not co-extensive for any other, and therefore burdensome, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product

and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SBC
Stacy B. Chen
May 5, 2004

James C. Housel
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